UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

November 19, 2004

MEMORANDUM

Subject: Efficacy Review for Lysol® Brand Disinfectant S.A. Cleaner, Reg. No. 676-55;
DP Barcode: D309417

From: Marcie Wawzysko, Microbiologist — Marcie Wawzysko 11/19/04
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Applicant: Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Formulation from the Label:

Active Ingredient(s)	% by wt.
Citric Acid	2.50%
Other ingredients	97.50%
Total	100.00%

I. BACKGROUND

The product, Lysol® Brand Disinfectant S.A. Cleaner, is an Agency approved hospital use disinfectant (bactericidal, tuberculocidal and virucidal) and non-food contact surface sanitizer. The applicant has submitted eight alternate formulations for fragrance additions to the product and is submitting confirmatory efficacy data for *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* to support the hospital disinfectant claim. Testing was conducted by Reckitt Benckiser Inc. Microbiology Laboratory, located at One Philips Parkway, Montvale, New Jersey 07645.

The data package contained a letter from the applicant to the agency (dated April 7, 2004), Agency form 8570-1 (Application for Pesticide), the last accepted label (dated July 8, 2003), and one submitted study with Statements of No Data Confidentiality Claims, Good Laboratory Practice, and Quality Assurance.

II. USE DIRECTIONS

The product is intended for use as a hospital grade disinfectant on hard, non porous, non-food contact inanimate environmental bathroom surfaces in health care facilities, homes, schools, hospitals, and other public places. Treated surfaces may include tile, tubs, sinks, shower doors, fixtures, toilets and other surfaces made from glazed porcelain, glazed ceramic, stainless steel, chrome, glass, synthetic marble, and laminated plastic.

The last accepted label provides the following directions for use of the product: "If the surfaces are visibly dirty, follow cleaning directions first; then spray on (apply on) surface to be cleaned until thoroughly wet. Leave for 10 minutes. Wipe with a damp cloth or sponge." The label also includes directions for cleaning, mold control, special HIV-1 precautions, sanitization, and deodorization.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Confirmatory Efficacy Data Requirements for Hospital or Medical Environment Disinfectants.

In certain situations an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formulation. Data must be developed on the applicant's finished product when test methodology utilized in deriving the original supporting efficacy data were modified. Confirmatory testing is only required at the most stringent dilutions and conditions of efficacy listed on the label. Either the AOAC Use-Dilution Method for liquid products, or the AOAC Germicidal Spray Products Test must be employed using 10 carriers for each of 2 samples representing 2 different batches against each of *Salmonella choleraesuis* ATCC 10708, *Staphylococcus aureus* ATCC 6538, and *Pseudomonas aeruginosa* ATCC 15442. Performance standards for confirmatory

efficacy testing require killing on all carriers. The above Agency standards can be found in DIS/TSS-5.

IV. SUMMARY OF SUBMITTED STUDIES

MRID 462491-01 "Hospital Type Disinfectant Efficacy Testing In the Presence of Organic Soil" for Lysol® Brand Disinfecant S.A. Cleaner by Kyle T. Smith. Study conducted by Reckitt Benckiser Inc. Microbiology Laboratory, Study Identification Number 2003-0065. Study completed September 17, 2003.

This confirmatory study was conducted against *Staphylococcus aureus* ATCC 6538, *Salmonella choleraesuis* ATCC 10708, and *Pseudomonas aeruginosa* ATCC 15442. Two lots of the product (Batch Nos. 883-133 and 883-135) were tested following methods of the AOAC Germicidal Spray Products as Disinfectants test as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. The test substance was received ready to use, and horse serum was added to the inoculum to create a 5% organic soil load. All cultures underwent at least three consecutive daily transfers. Sterile glass slide carriers were inoculated with 0.01mL of the 48 hour old test cultures and allowed to dry for 40-42 minutes at 32.5-37.5°C. Carriers were sprayed by 2 to 4 pumps of the test substance at a distance of 6-8 inches and left in contact for 10 minutes at 21.2-23.0°C. Following treatment, carriers were subcultured into 20mL of Letheen broth and incubated 48 hours at 32.5-37.5°C after which time, tubes were scored for the absence or presence of growth. Controls included those for inoculum count, carrier count, viability, test organism confirmation, neutralizer effectiveness, and sterility.

V. RESULTS

Results Expressed as Subcultures Showing Growth/ Total Tested

Organism	Avg. Carrier Count CFU/mL	Growth	
		883-133	883-135
Staphylococcus aureus	9.0×10^6	0/10	0/10
Salmonella choleraesuis	6.0×10^5	0/10	0/10
Pseudomonas aeruginosa	9.5×10^5	0/10	0/10

All controls met the criteria for a valid test. Neutralization and viability controls were positive for growth. Sterility controls were negative for growth. Test results were positive for identification of test organisms.

VI. CONCLUSIONS

The submitted efficacy data (MRID 462491-01) **supports** the use of the product, Lysol® Brand Disinfectant S.A. Cleaner when tested at full strength, in the presence of organic soil, on hard, non-porous inanimate surfaces for a contact time of 10 minutes at room temperature.

VII. RECOMMENDATIONS

The last accepted label claims that the product is an effective hospital and general disinfectant and one step cleaner for use on hard, non-porous, non-food contact surfaces for a contact time of 10 minutes at room temperature. **This claim is supported by the submitted data.** The data provided indicates that the addition of the alternate formulas for fragrance did not adversely affect the efficacy of the product.